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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of

results of federally-funded research and development. Foreign patent applications are

filed on selected inventions to extend market coverage for companies and may also be

available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of

the patent applications listed below may be obtained by communicating with the

indicated licensing contact at the Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD,

20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required

to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

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Small Molecule Imaging Of Fungi By Positron Emission Tomography Scanning Description of Technology:

This technology relates to the field of radioactive, isotopically-labeled calcofluor derivatives and uses of such compounds to detect a broad spectrum of filamentous fungi including pathogenic species such as <u>Aspergillus</u> and <u>Mucorales</u>, by diagnostic imaging methods such as positron emission tomography (PET) scanning.

Aspergillosis and other filamentous fungal infections are increasingly common fungal lung infection with high mortality rates (over 50%) in immune compromised patients, such as those receiving chemotherapy, stem cell/organ transplantation, or HIV patients. One-year survival of the infected patients ranges from 59% (organ transplant recipients) to as low as 25% (stem cell transplant recipients). Delayed diagnosis and therapy are likely to lead to poor outcomes and death. This disease is often first detected as nodules on CT scans. A diagnosis is typically made following invasive lung bronchoscopy or biopsy. However, as these patients are immunocompromised, these invasive procedures may themselves lead to significant complications and infections. Therefore, to enable timely treatment and minimize complications, there is a critical need for non-invasive means to detect and diagnose fungal infections.

The calcofluor derivatives disclosed in the patent application may be utilized as imaging agents specific for fungal infections and could potentially become a standard, non-invasive procedure in the work-up of immunocompromised patients with lung infections.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 C.F.R. Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

• Diagnostics of Aspergillosis and other filamentous fungal infections

Competitive Advantages:

- Non-invasive
- Low toxicity
- Specific for <u>Aspergillus</u>

Development Stage:

• In vivo data available (animal)

Inventors: Peter R. Williamson (NIAID), Dale O. Kiesewetter (NIBIB), John C. Panepinto (University of Buffalo), and Jin Qiu (NIAID).

Publications:

- 1. Palmer GE, et al., The diverse roles of autophagy in medically important fungi, Autophagy. 2008 Nov; 4(8):982-8. [PMID 18927489]
- 2. Panepinto JC, et al., Deletion of the Aspergillus fumigatus gene encoding the Rasrelated protein RhbA reduces virulence in a model of invasive pulmonary aspergillosis, Infect Immun. 2003 May; 71(5):2819-26. [PMID 12704156]
- 3. Desoubeaux D, et al., Diagnosis of invasive pulmonary aspergillosis: updates and recommendations, Med Mal Infect. 2014 Mar; 44(3):89-101. [PMID 24548415]

Intellectual Property: HHS Reference Nos. E-449-2013/0,1—U.S. Provisional

Application No. 61/894,754, filed October 23, 2013; PCT Application No.

PCT/US2014/061917, filed October 23, 2014 (published as WO 2015/061540 on April

30, 2015); European Application No. 14800182.9, filed October 23, 2014 (pending);

Australian Application No. 2014340035, filed October 23, 2014 (pending); Canadian

Application No. 2927952, filed October 23, 2014; and U.S. Application No. 15/030,554,

filed April 19, 2016 (pending).

Licensing Contact: Dr. David Yang, 240-627-3413; polung.yang@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious

Diseases is seeking statements of capability or interest from parties interested in

collaborative research to further develop, evaluate or commercialize for development of

this invention. For collaboration opportunities, please contact Dr. David Yang, 240-627-

3413; polung.yang@nih.gov.

Dated: February 6, 2017

Suzanne Frisbie,

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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